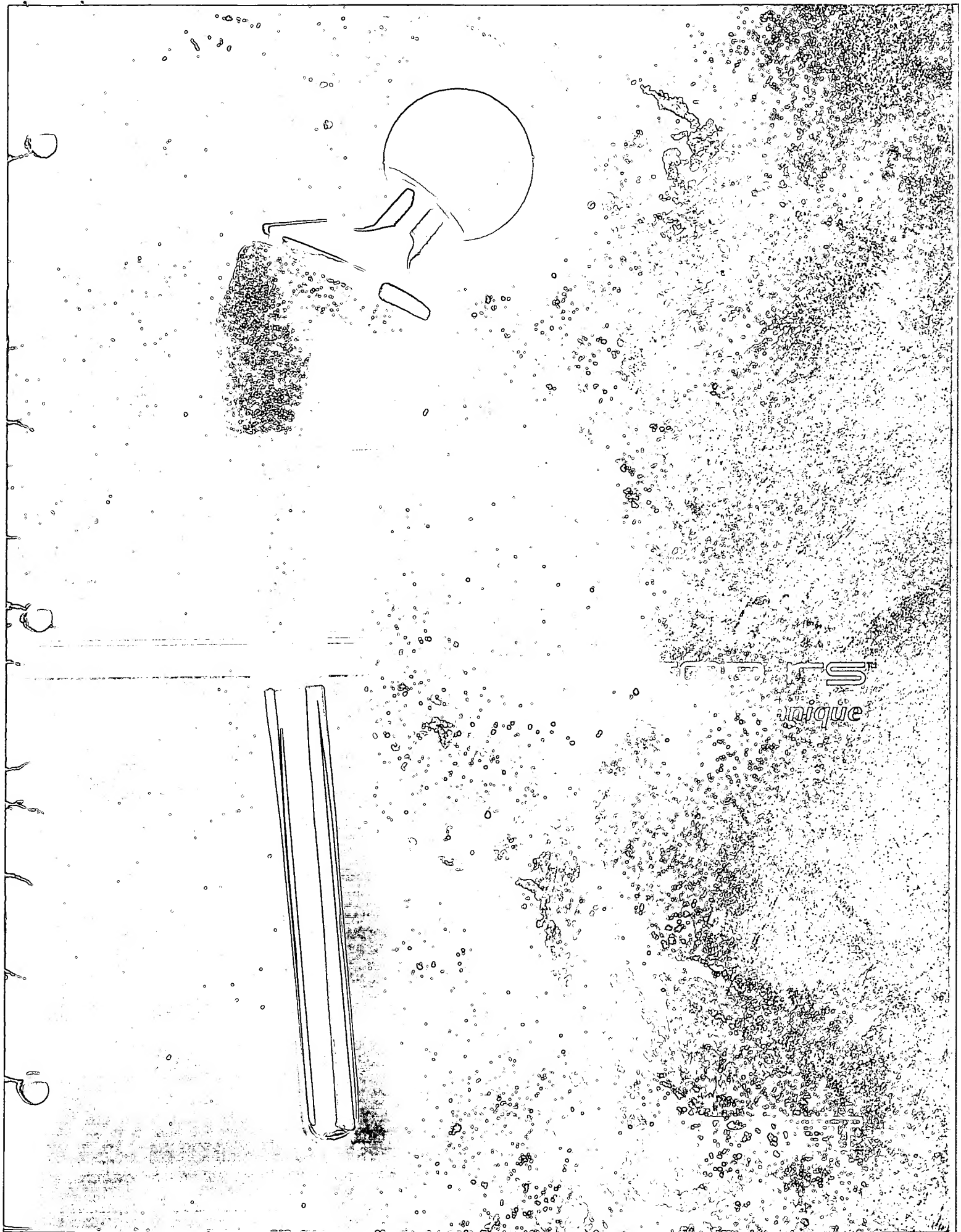
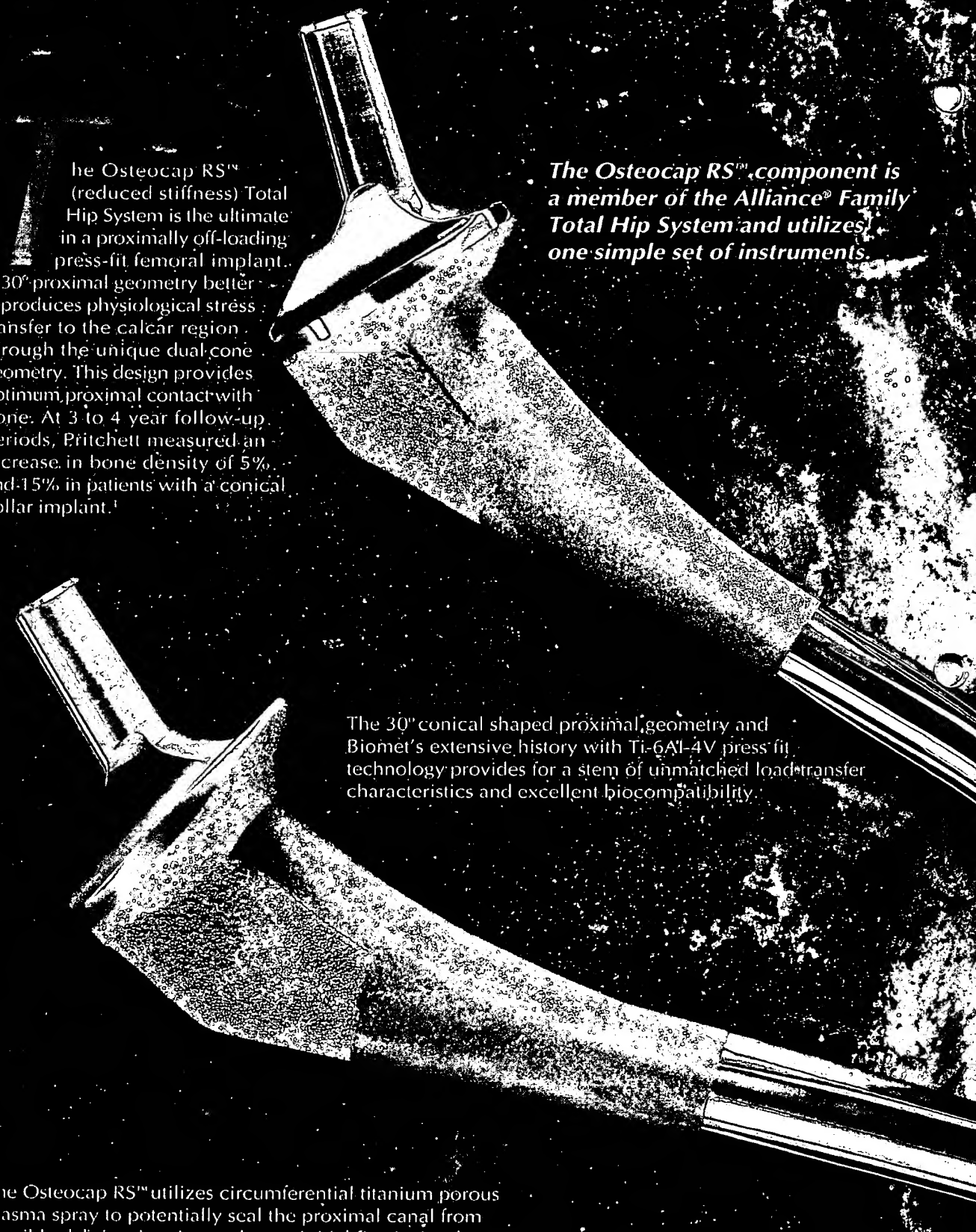


# Exhibit A





The Osteocap RS™  
(reduced stiffness) Total  
Hip System is the ultimate  
in a proximally off-loading  
press-fit femoral implant.

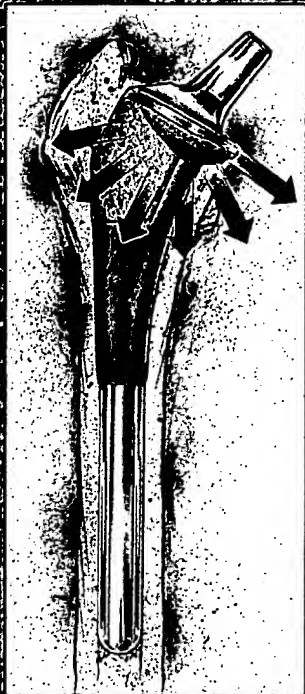
A 30° proximal geometry better  
reproduces physiological stress  
transfer to the calcaneal region  
through the unique dual cone  
geometry. This design provides  
optimum proximal contact with  
bone. At 3 to 4 year follow-up  
periods, Pritchett measured an  
increase in bone density of 5%  
and 15% in patients with a conical  
collar implant.<sup>1</sup>

*The Osteocap RS™ component is  
a member of the Alliance® Family  
Total Hip System and utilizes  
one simple set of instruments.*

The 30° conical shaped proximal geometry and  
Biomet's extensive history with Ti-6Al-4V press fit  
technology provides for a stem of unmatched load transfer  
characteristics and excellent biocompatibility.

The Osteocap RS™ utilizes circumferential titanium porous  
plasma spray to potentially seal the proximal canal from  
possible debris migration, enhance initial fixation and  
provide an excellent surface for ingrowth.<sup>2</sup>

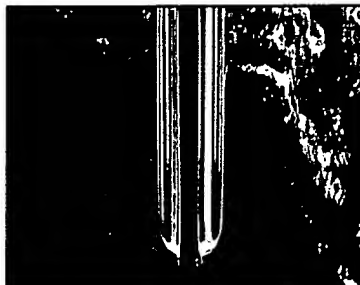
# Osteocap RS™



## Proximal Geometry

The 30° conical shaped proximal geometry coupled with a 3° bi-planar taper produces an intimate seal between the implant and the conically reamed bone. This provides physiologic proximal load transfer to the calcar region and enhances rotational stability.

The initial stability of the press-fit 30° proximal geometry has been shown to be superior to a collarless press-fit stem. Fischer, et al., found the conical collared design to be in excess of 3.7 times more stable than an identical collarless implant.<sup>3</sup>



## Distal Geometry

The coronal slot reduces stem stiffness and minimizes distal point loading, allowing the implant to better simulate the modulus of bone. The Osteocap RS™ also incorporates four distal flutes which enhance the rotational stability of the implant.



<sup>1</sup> Pritchett J.W., "Femoral Bone Loss Following Hip Replacement: A Comparative Study." *Clinical Orthopaedics*, No. 314, pp. 156-161, May 1995.

<sup>2</sup> Multi-Center Study—Information on file at Biomet, Inc., Warsaw, Indiana.

<sup>3</sup> Fischer K.J., et al; "In Vitro Study of Initial Stability of a Conical Collared Femoral Component." *The Journal of Arthroplasty*, Vol. 7, Supplement 1992.

*The porous coated devices depicted in this brochure are marketed for non-cemented use in skeletally mature patients undergoing primary hip replacement surgery as a result of noninflammatory degenerative joint disease.*

*Osteocap RS is a trademark of Biomet, Inc.*

# ***Surgical Technique***

by John Fenning, M.D.

## ***Preoperative Planning Templating***

Preoperative planning can easily be performed utilizing templates for femoral sizing. It is recommended that a radiographic marker be used to assess X-ray magnification on an individual basis so that the proper templates can be selected.

The appropriate femoral template which best fills the canal both proximally and distally on both the A/P and lateral projections is chosen. As a point of reference, the position of the neck cut should be related to the obturator externus fossa, which can be observed as a confluence of lines coming together approximately 1 cm inferior to the tip of the greater trochanter. If that point is used as a reference, the femoral head resection

can begin slightly higher than that point, but should not go below that point of confluence.

In the vast majority of cases, the line drawn perpendicular to the femoral shaft axis through the tip of the greater trochanter will intersect the center of the femoral head. In cases of coxa vara or coxa valga, this may vary and either the level of the neck cut or selection of neck length can be varied to achieve the desired leg length equalities. Using the technique of varying the level of neck cut in combination with the selection of appropriate neck length, correct leg length and normal lateral offset can be re-established.

## ***Surgical Approach***

The recommended surgical exposure is a posterolateral approach as it affords excellent exposure of the femoral shaft for canal preparation. Detachment of the short external rotators in combination with a posterior capsule allows for later reattachment of the structures.

*This brochure is presented to demonstrate the surgical technique utilized by John Fenning, M.D., Orthopedic Surgeon, Ft. Myers, Florida. Biomet, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and utilizing the appropriate techniques for implanting the prosthesis in each individual patient. Biomet is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.*



## Step 1

### Preparing the Femoral Head Resection Level

Once the hip is dislocated, the level of the neck resection can be measured from the obturator externus fossa. That fossa is identified by the attachment of the obturator externus tendon to the base of the greater trochanter. This can be palpated as a small depression. Position the cutting guide so that the direction of the cut is aligned with the fossa. This creates an unerring point of reference. More or less of the femoral neck can be cut if there is an unusual anatomical variation of the length or offset of the neck. The femoral neck cut can be made by either using the Provisional/impactor as a template (Figure 1), or by using the femoral resection templates (Figure 2). The neck cut (Figure 3) is made slightly horizontal; which will allow the conical neck reamer to form the proximal geometry.

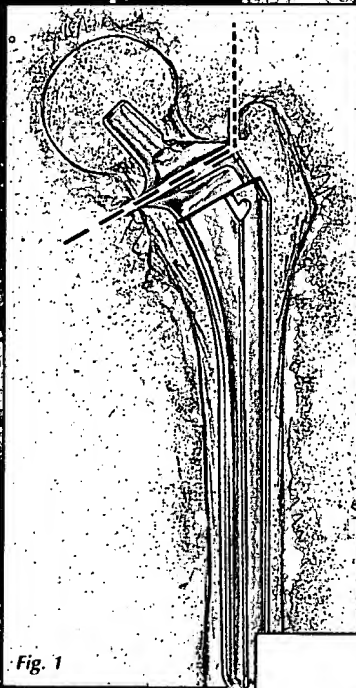


Fig. 1



Fig. 2



Fig. 3

## Step 2

### Acetabular Preparation

The acetabulum is prepared in the standard fashion utilizing any of Biomet's surgical techniques and corresponding acetabular components, or the surgeon may choose to utilize any technique deemed suitable.

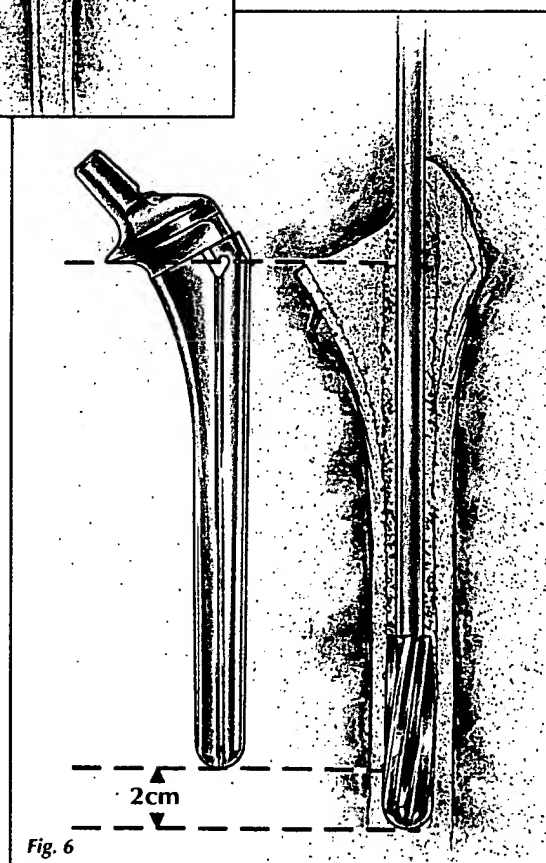
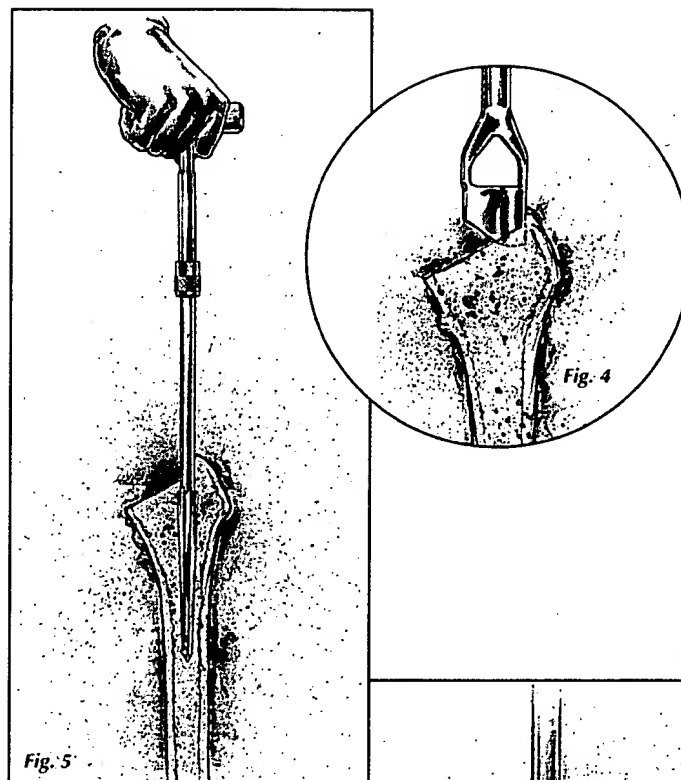
## Step 3

### Femoral Preparation Cylindrical Reaming

A hollow chisel is used to identify the femoral canal (Figure 4). If the hollow chisel is placed slightly anterior and medial to the greater trochanter, removal of the bone in that location will provide a direct entrance to the femoral shaft. The femoral canal can then be further opened with a hand held starter reamer (Figure 5) or an 8mm cylindrical reamer. The reamer is advanced slowly to open the canal. The appropriate cylindrical reaming depth is established by referencing the provisional/impactor and corresponding collar/neck provisional of the templated size (Figure 6). Assure that the cylindrical reamer is advanced a minimum of 2cm beyond the distal tip of the provisional/impactor. Increase the reamer size by 2mm increments until the cutting flutes encounter cortical bone. **The final cylindrical reamer size should be 1mm larger than the implant size. This will provide a 1mm flute engagement into the cortical bone\* (1/2mm per side).**

**Example:** When implanting a 13mm stem, cylindrically ream distally to 14mm.

*\*Be sure that the cylindrical reamer is kept central within the canal to avoid a coxa vara or coxa valga situation.*



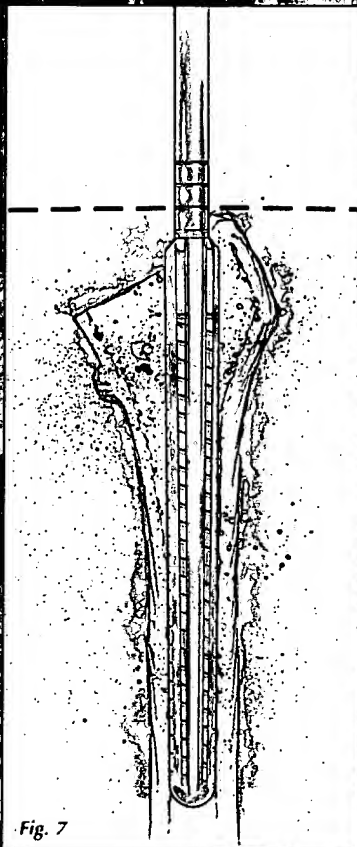
## Step 4

### *Femoral Preparation Tapered Reaming*

Initiate tapered reaming by selecting the tapered reamer which is one size less than the last cylindrical reamer used. The reamer is advanced slowly within the canal until the appropriate depth groove on the reamer shank is to the top of the greater trochanter (Figure 7).

As the reamer is withdrawn, lateral pressure is exerted to ensure proper lateralization within the canal. The reamer's tapered design and side cutting feature help to avoid notching of the endosteal wall.

Example: If the last cylindrical reamer used is 14mm, then a 13mm tapered reamer is required.





## Step 5a

### Femoral Preparation Broaching the Proximal Canal (Optional)

Should the surgeon determine that the quality of bone is suitable, *impacting in place of broaching* may be utilized to shape the proximal portion of the femur.

Once appropriate cylindrical and tapered reaming has been completed, broaching can be initiated with a 9mm broach. It is important that the broach is oriented so that the mediolateral axis of the broach is parallel to the anatomic mediolateral axis of the femoral neck (Figure 8). This will help to ensure maximum proximal canal fill. The broach is impacted below the resection level to the appropriate mark "R" on the Alliance broach handle (Figure 9). Continue broaching by increments of 2mm until the broach size equals the last tapered reamer size.

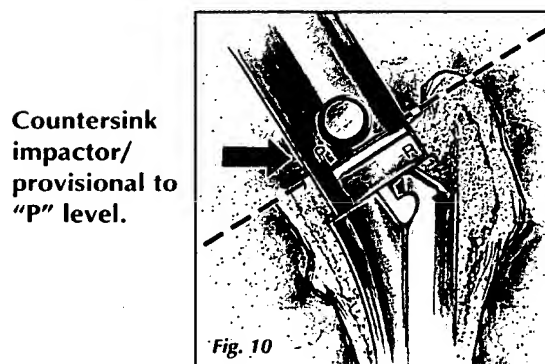
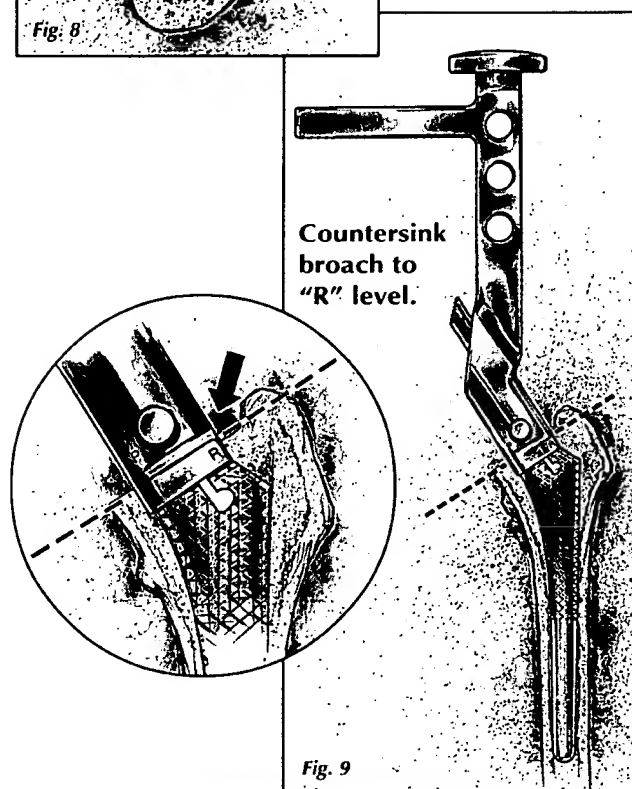
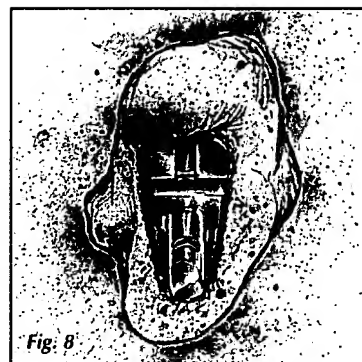
Example: For a 13mm tapered reamer, final broach size is 13mm. This size also correlates to the size of the implant.

## Step 5b

### Impacting

After broaching is complete or if broaching will not be utilized, the 9mm provisional/impactor is inserted to the level "P" on the Alliance® broach handle. Continue impacting, increasing in size by 2mm until the provisional/impactor equals the size of the last tapered reamer.

Example: For a 13mm tapered reamer, finish impacting with a 13mm provisional/impactor (Figure 10).



**Conical reaming must be performed off the provisional/impactor.**

Remove the broach handle, leaving the provisional/impactor in the femoral canal. Position the correct size conical neck reamer and place it onto the provisional/impactor. The conical neck reamer is used to prepare the femur for the 30° proximal geometry. Rotation of the conical reamer on the post of the provisional/impactor should commence prior to contact with the femur to avoid possible calcar fractures. Conically ream until the reamer bottoms out on the provisional/impactor. The post of the provisional/impactor will appear in the circular window when fully seated (Figure 11).

Conical reamers are available in three sizes: Medium, Large, and X-Large. The medium is used with the 9mm stems. The large is used with the 11mm, 13mm and 15mm stems. The X-large is used with the 17mm stems.

**Example: For a 13mm provisional/impactor, use a large conical reamer.**

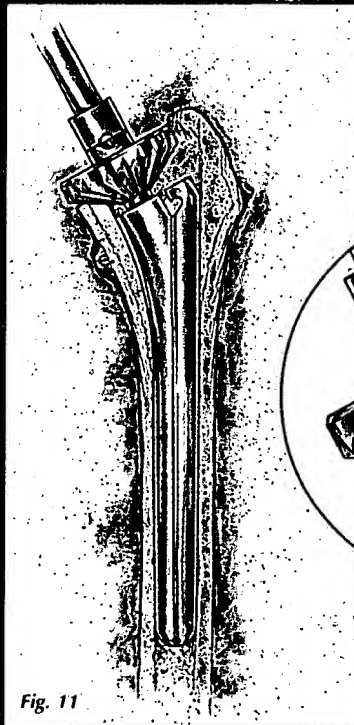
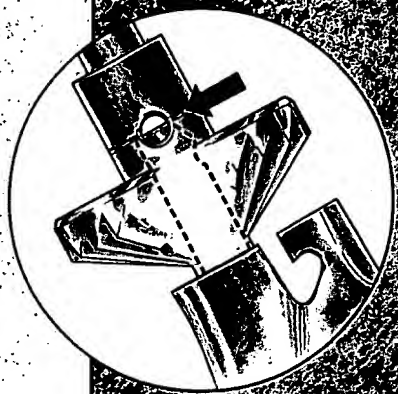


Fig. 11



## Step 7

### *Trial Reduction for the Osteocap RS™*

The Osteocap RS system utilizes the provisional/impactor as a trial that matches the implant dimensions minus the porous coating and flutes. This allows seating of the trial prosthesis without the worry of the trial becoming fixed in the femur.

With the final provisional/impactor in place and the conical reaming complete, select the corresponding collar/neck trial size and insert with the bullet tip inserter (Figure 12). The collar/neck trial should seat flush against the calcar with the provisional/impactor post protruding through the neck of the collar/neck provisional (Figure 13). Mark the medial calcar with a bovie through the slot provided in the collar/neck trial. This will assist with aligning the implant during insertion (Figure 14). With the trial in place, provisional heads are selected and trial reduction is done to determine the appropriate neck length (Figure 15).

Example: Final provisional/impactor size is 13mm, select 13mm collar/neck trial.

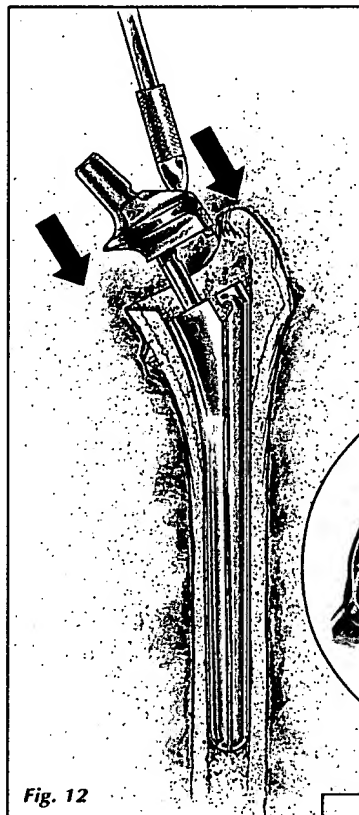


Fig. 12

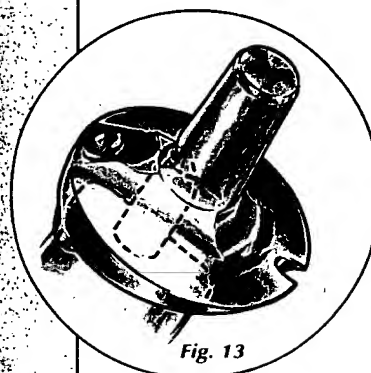


Fig. 13



Fig. 14

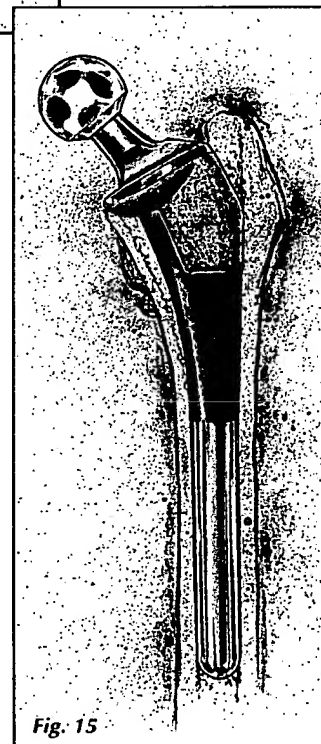


Fig. 15

## Step 3.

### Implant Insertion

To implant the femoral stem, the inserter/extractor is threaded into the implant. While impacting the stem into the canal, care should be taken to align the "V" groove of the stem with the mark on the calcar (Figure 16). This will place the coronal slot within the coronal plane (Figure 17). The 30° proximal geometry should seat flush against the medial, anterior and posterior calcar and the lateral shoulder should seat against the greater trochanter. Rotational stability is ensured with the collar, porous coating and distal flutes.

After fully seating the femoral component, another trial reduction can be accomplished prior to impacting the modular head. Provisional heads in seven neck lengths ensure proper leg length and stability. The appropriate modular head is selected and impacted onto the femoral neck. The hip is now ready to be reduced (Figure 18).

Drains are placed deep in the joint and the capsule and short external rotators can be repaired. The remaining closure can be done in a routine fashion.



Fig. 16

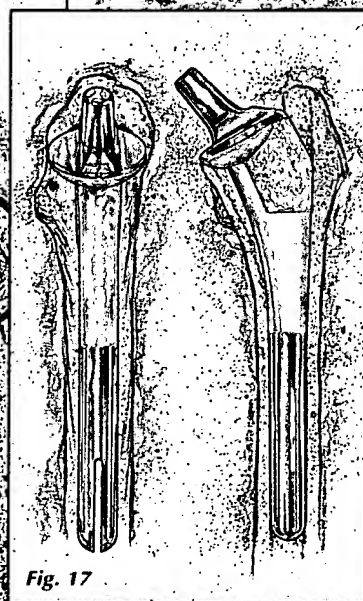


Fig. 17



Fig. 18

## Ordering Information

Osteocap RS™ Femoral Component and Instrumentation									
Stem Size	Implants	Stem Length	Provisional/Impactor	Cylindrical Reamer	Tapered Reamer	Broach	Provisional/Impactor	Conical Reamer	Conical Ctr/Nk Trials
9mm	110109	145mm	31-110109	10mm	9mm	9mm	9mm	Med	9mm
11mm	110111	150mm	31-110111	12mm	11mm	11mm	11mm	Lg	11mm
13mm	110113	155mm	31-110113	14mm	13mm	13mm	13mm	Lg	13mm
15mm	110115	160mm	31-110115	16mm	15mm	15mm	15mm	Lg	15mm
17mm	110117	165mm	31-110117	18mm	17mm	17mm	17mm	X-Lg	17mm

*The following instruments are needed in addition to standard Alliance® instrumentation.*

### Bullet Tip Cylindrical Reamers

474832	8mm
474836	9mm
474840	10mm
474844	11mm
474848	12mm
474852	13mm
474856	14mm
474860	15mm
474864	16mm
474868	17mm
474872	18mm

### Conical Collar Reamers

31-110140	Medium
31-110141	Large
31-110142	X-Large

### Integral Reduced Proximal Profile Broaches

31-473618	9mm
31-473619	11mm
31-473666	13mm
31-473667	15mm
31-473668	17mm

### Conical Collar/Neck Trials

31-110159	9mm
31-110161	11mm
31-110163	13mm
31-110165	15mm
31-110167	17mm

### Femoral Resection Guides

31-110129	9mm
31-110130	11mm
31-110131	13mm
31-110132	15mm
31-110133	17mm

*Note: Conical reaming must be done off the provisional/impactor.*

### Rasp Handle Style "A" (Push Button)

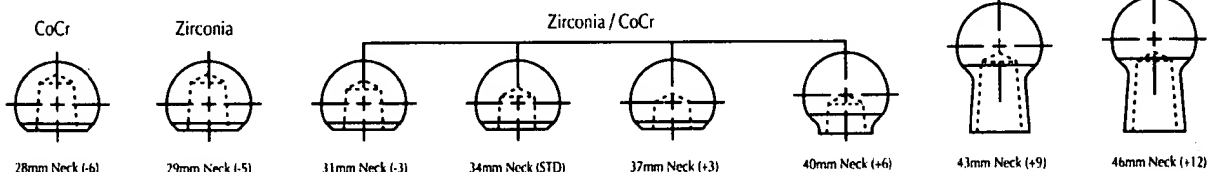
31-473700

### Osteocap RS™ Femoral X-Ray Templates

110190

*Standard Alliance Tapered Reamers, Inserters, Trial Heads and Extraction Instruments are also needed.*

## Modular Head Options (26mm (CoCr only), 28mm, 32mm)



(22mm CoCr heads also available in Std., -3mm, -5mm)





**Osteocap RS™ Femoral Components**

Size	Stem Length	Neck Angle	Horizontal Offset (mm)								Vertical Offset (mm)							
			-6	-3	Std.	+3	+6	+9	+12	-6	-3	Std.	+3	+6	+9	+12		
9mm	145mm	135°	35.8	37.9	40.0	42.1	44.2	46.4	48.5	28.3	30.4	32.5	34.6	36.7	38.9	41.0		
11mm	150mm	135°	36.8	38.9	41.0	43.1	45.2	47.4	49.5	29.3	31.4	33.5	35.6	37.7	39.9	42.0		
13mm	155mm	135°	36.8	38.9	41.0	43.1	45.2	47.4	49.5	29.3	31.4	33.5	35.6	37.7	39.9	42.0		
15mm	160mm	135°	37.8	39.9	42.0	44.1	46.2	48.4	50.5	29.3	31.4	33.5	35.6	37.7	39.9	42.0		
17mm	165mm	135°	37.8	39.9	42.0	44.1	46.2	48.4	50.5	29.3	31.4	33.5	35.6	37.7	39.9	42.0		

## This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.





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